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14. ABSTRACT <p>The military has an increasing number of patients with combat-related impairments that contribute to suboptimal medication self-management. These impairments include TBI, PTSD, poly-trauma, and mental health issues. A significant number of these patients are in transitional care outpatient settings, lacking adequate clinical staff to provide the necessary pharmacy services. The objective of this study is to evaluate whether the use of a TelePharmacy robotic remote medication dispensing unit (TRMDU), in addition to medication review in patients assigned to WTUs, VA hospitals, and similar units, leads to improved outcomes and reduced health care costs for patients when compared with medication review alone. This study will use a prospective non-randomized repeated measures design with two sites using a control condition for 12 weeks, followed by a 12-week TRMDU intervention condition. The third site will serve as intervention only.</p>					
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INTRODUCTION

This study involves a FDA cleared remote medication management device, 21 CFR 880.6315, which provides unit dose delivery of medications across the continuum of care. The Telepharmacy Robotic Medication Dispensing Unit (TRMDU), developed by INRange® Systems, Inc., is a Class II medical device, located in the home, outpatient setting, or in the field, and consists of a medication delivery unit and two-way communication software that allows a health care professional to remotely manage prescriptions stored and released by the patient-operated delivery unit. The delivery unit is approximately the size of a bread box, and it plugs into a standard power outlet.

We have continued to develop the protocol that will assess this TRMDU unit in subjects with traumatic brain injury (TBI), post-traumatic stress disorder (PTSD), multiple traumatic brain injury (MTBI), or Polytrauma. The objective of this study is to evaluate whether use of a TRMDU, in addition to medication review in patients assigned to WTUs, VA hospitals, and similar units, leads to improved outcomes and reduced health care costs for patients when compared with medication review alone.

BODY

IRB Preparation and Application (Jan 2010 – Dec 2010)

The study was approved by institutional IRB's at the University of Illinois at Chicago on March 25, 2010 and Columbia College of Nursing on October 25, 2010. It was submitted for review to the IRB at NMSCD for the Camp Pendleton site on September 16, 2010, undergone a preliminary review, and has been resubmitted.

Ongoing Study Site Recruitment, Visits, and Development (Jan 2010 – Dec 2010)

The program implementation and evaluation will still be conducted at three sites: 1) James A. Haley VA Hospital and Polytrauma Facility in Tampa Bay, Florida (Tampa VA); 2) Naval Hospital Camp Pendleton, in Camp Pendleton, California (Camp Pendleton); and 3) Ireland Army Community Hospital, Fort Knox, Kentucky (Fort Knox).

A CRADA was prepared between TATRC and Naval Hospital Camp Pendleton outlining the site responsibilities and support. A staffing management plan was prepared to support the CRADA. The CRADA was signed and executed on June 24, 2010.

Planning committee meetings were held in Atlanta on March 1, 2010 and San Antonio on May 19, 2010. During the Atlanta meeting, the discussion focused primarily on study progress and budget. Discussions also focused on next steps, such as hiring of site research personnel, delivery and preparation of the TRMDU's, and study impact on sites. DIACAP certification of the TRMDU (EMMA®) System is a requirement of the TRMDU study, and progress towards obtaining this certification was discussed at the Atlanta and San Antonio meetings. Presently, INRange is in the final review stages of our Navy DIACAP C&A (Certification and Accreditation Process) package with the Navy Information Assurance team, and expects final approval early 2011.

At the San Antonio meeting study progress and budget were once again addressed and committee members updated on study progress. Discussions were held on the transfer of Naval Hospital Camp Pendleton site PI status from LCDR Caine Kras to Angelica Klinski. Also discussed were details regarding TRMDU use, general procedures for repackaging medications, and site research assistance clearance and training. Dr. Touchette, Dr. Winters, and LCDR Klinski attended a site visit at Fort Carson on September 22, 2010 to view the TRMDU in use and talk with clinicians and patients who

were using the device. Valuable insights were gained regarding the importance of standardizing TRMDU settings, information contained in TRMDU reports, and development of the policy and procedures for optimizing the TRMDU during the study. A site visit to Camp Pendleton was conducted on August 31, 2010 with the goal of completing the site IRB application and addressing any issues identified by LCDR Klinski.

Protocol

No significant changes were made to the protocol during the period Dec 25, 2009 – Dec 25, 2010. A copy of the current study protocol is appended to this report.

CRADA and Statement of Work (Jan 2010 – Jun 2010)

A CRADA was developed outlining the 1) background; 2) roles, responsibilities, and relationships of TATRC, Naval Hospital Camp Pendleton, NMCSO, and INRange; and 3) ownership and use of physical property for the TRMDU study. Additional articles included termination, contacts, security, use of protected health information, and liability. The agreement also contained an appendix outlining the activities that will be conducted at the Naval Hospital Camp Pendleton site by research assistants and the necessary support for conducting the study. The CRADA is appended to this report.

DIACAP Preparation and Submission

INRange commenced preparation of a comprehensive DIACAP C&A package Q2/2009. At the present time, the following items, artifacts and activities have been submitted and are being reviewed by the Navy Information Assurance team:

- System Identification Profile (SIP)
- DITSCAP baseline documentation
- Navy POA&M (Plan of Action and Milestones)
- Continuity of Operations Plan (COOP)
- Disaster Recovery “Table Top” exercise
- Enclave and system diagrams
- All servers have been locked down to STIG compliance and scanned with Retina
- Remediation of CAT 1 and Cat 2 Retina scan findings
- All required artifacts have been submitted
- Data Center On-site Audit completed
- Incident Response Plan (made available to auditor)

KEY RESEARCH ACCOMPLISHMENTS

To date, the following has been completed:

- Protocol
- Identification of the participating sites
- Obtaining required approvals and contracts for Naval Hospital Camp Pendleton
- Gaining IRB approval at University of Illinois at Chicago and Columbia College of Nursing

To date, we have made considerable progress in the following:

- Preparation and submission of the IRB documents to Naval Hospital Camp Pendleton
- Preparation of IRB documents for Fort Detrick submission

REPORTABLE OUTCOMES

We are currently pursuing approval to begin the study. At present there are no reportable outcomes. We expect that, when completed, this study will generate at least one and possibly two manuscripts on the effectiveness of the TRMDU on adherence and outcomes assessed in this study for this population. Publication of these manuscripts will be pursued in major, peer-reviewed medical journals.

CONCLUSION

Findings from several studies have shown that better medication adherence leads to better outcomes, fewer hospitalizations and emergency department visits, and greater QOL. Use of the TRMDU may improve medication adherence; reduce DRPs; and positively impact pain, psychological, and QOL measures for veterans with TBI, PTSD, and/or polytrauma. In addition, health care costs and hospitalizations may be reduced. If findings from this study support the hypotheses, use of the TRMDU may be a valuable intervention and lay the groundwork for applications of the TRMDU with this population in both the Warrior Transition Units and in community settings. In addition, those individuals in rural settings with limited access to major medical centers and other populations with documented difficulty with medication adherence may benefit from such a device. This study will serve to lay the groundwork for additional funding to assess the effectiveness of the TRMDU in these settings.

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